

We claim:

1. A crystalline form of cetirizine monohydrochloride.
2. The crystalline form of cetirizine monohydrochloride of claim 1 having an X-ray diffraction pattern, expressed in terms of 2θ angles and obtained with a diffractometer equipped with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2θ angles of 12.97 ± 0.09 , 22.94 ± 0.09 , 20.41 ± 0.09 , 17.35 ± 0.09 , 19.15 ± 0.09 , 8.75 ± 0.09 , 14.19 ± 0.09 , 17.01 ± 0.09 , 28.28 ± 0.09 , 21.61 ± 0.09 and 9.84 ± 0.09 degrees.
3. The crystalline form of cetirizine monohydrochloride of claim 1, wherein said X-ray diffraction pattern includes peaks with 2θ angles of about 12.968, 22.941, 20.405, 17.348, 19.148, 8.749, 14.189, 17.01, 28.28, 21.610, and 9.842.
4. The crystalline form of cetirizine monohydrochloride of claim 1 having substantially the same X-ray diffraction pattern as shown in Figure 1.
5. The crystalline form of cetirizine monohydrochloride of claim 1 having an infrared absorption spectrum comprising absorption bands at about 3427 cm^{-1} , about 2839 cm^{-1} , about 2587 cm^{-1} , about 1741 cm^{-1} , and about 1600 cm^{-1} .
6. The crystalline form of cetirizine monohydrochloride of claim 1 having substantially the same infrared spectrum as shown in Figure 2.
7. The crystalline form of Cetirizine monohydrochloride of claim 1 having a differential scanning calorimetry thermogram, which exhibits an endotherm peak at about 186°C .

8. The crystalline form of cetirizine monohydrochloride of claim 1 having substantially the same differential scanning calorimetry thermogram as shown in Figure 3.

9. A composition comprising cetirizine monohydrochloride as a solid, wherein at least 80% by weight of said solid cetirizine monohydrochloride is in a crystalline form.

10. The composition of claim 9, further comprising at least one additional form of solid cetirizine different from cetirizine monohydrochloride, said at least one different form of solid cetirizine being selected from the group consisting of cetirizine free species and cetirizine dihydrochloride.

11. The composition of claim 10, wherein said at least one different form of solid cetirizine is cetirizine dihydrochloride being present in the amount of from about 80% to about 99.5% by weight with respect to the combined weight of all solid forms of cetirizine in the composition.

12. The composition of claim 11, wherein said crystalline form of cetirizine monohydrochloride is present in the amount of from about 0.1% to about 5% by weight with respect to the combined weight of all solid forms of cetirizine in the composition.

13. The composition of claim 9, which is in the form of bulk powder suitable for use as an active ingredient in pharmaceutical formulations.

14. The composition of claim 9, where said crystalline cetirizine monohydrochloride has an X-ray diffraction pattern, expressed in terms of 2θ angles and obtained with a diffractometer equipped with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group

consisting of peaks with 2 theta angles of 12.97 ± 0.09 , 22.94 ± 0.09 , 20.41 ± 0.09 , 17.35 ± 0.09 , 19.15 ± 0.09 , 8.75 ± 0.09 , 14.19 ± 0.09 , 17.01 ± 0.09 , 28.28 ± 0.09 , 21.61 ± 0.09 and 9.84 ± 0.09 degrees.

15. The composition of claim 9, wherein at least 90% by weight of said solid cetirizine monohydrochloride is in said crystalline form.

16. The composition of claim 9, wherein at least 95% by weight of said solid cetirizine monohydrochloride is in said crystalline form.

17. The composition of claim 9, wherein at least 99% by weight of said solid cetirizine monohydrochloride is in said crystalline form.

18. A pharmaceutical composition, which comprises a pharmaceutically effective amount of a crystalline form of cetirizine monohydrochloride and one or more pharmaceutically acceptable carriers or diluents.

19. The pharmaceutical composition of claim 18, wherein said crystalline form of cetirizine monohydrochloride has an X-ray diffraction pattern expressed in terms 2 theta angles and obtained with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 12.97 ± 0.09 , 22.94 ± 0.09 , 20.41 ± 0.09 , 17.35 ± 0.09 , 19.15 ± 0.09 , 8.75 ± 0.09 , 14.19 ± 0.09 , 17.01 ± 0.09 , 28.28 ± 0.09 , 21.61 ± 0.09 and 9.84 ± 0.09 degrees.

20. The pharmaceutical composition of claim 18, which is a solid dosage form for oral administration.

21. The pharmaceutical composition of claim 20, wherein said solid dosage form is a tablet.

22. The pharmaceutical composition of claim 18, which further comprises of one or more additional active ingredients.

23. The pharmaceutical composition of claim 22, wherein said additional active ingredient is pseudoephedrine.

24. The pharmaceutical composition of claim 22, wherein said additional active ingredient is a leukotriene inhibitor.

25. The pharmaceutical composition of claim 22, wherein said additional active ingredient is an analgesic.

26. A process for preparation of a crystalline form of cetirizine monohydrochloride, said process comprising:

- a. providing a solid residue of crude cetirizine monohydrochloride;
- b. contacting said crude residue with a ketone solvent to cause separation of a solid mass; and
- c. isolating said solid mass thereby obtaining said crystalline form of cetirizine monohydrochloride.

27. The process of claim 26, further comprising providing an aqueous solution of cetirizine or salts thereof, adjusting the pH of said aqueous solution to between about 2 and about 4 with hydrochloric acid, extracting the acidified aqueous solution with a water immiscible organic solvent, and removing said water immiscible solvent to form said solid residue of cetirizine monohydrochloride.

26. 28. The process of claim 27, wherein said water immiscible organic solvent is selected from the group consisting of dichloromethane, chloroform, dichloroethane, ethyl acetate, and mixtures thereof.

29. The process of claim 27, wherein said water immiscible solvent is dichloromethane.

30. The process of claim 26, wherein said ketone solvent is selected from a group consisting of acetone, ethyl methyl ketone, methyl isobutyl ketone, and mixtures thereof.

31. The process of claim 26, wherein said ketone solvent is acetone.

32. The cetirizine monohydrochloride produced in accordance with the process of claim 26.

33. A method of treating allergic syndromes, which comprises administering a mammal in need thereof an effective amount of the compound of claim 1.

34. The method of claim 33, wherein said mammal is a human.

35. A process of making cetirizine dihydrochloride, which comprises:

a) providing a solid which is a cetirizine monohydrochloride in an amorphous form;

b) contacting said solid cetirizine monohydrochloride with a liquid phase containing water;

c) adding one or more equivalents of hydrochloric acid to said liquid phase so that said cetirizine monohydrochloride is converted to said cetirizine dihydrochloride.

36. The process of claim 35, further comprising dissolving said solid cetirizine monohydrochloride in an organic solvent prior to said contacting step.

37. The process of claim 35, wherein said organic solvent is selected from the group consisting of dichloromethane, chloroform, dichloroethane, ethyl acetate, methyl acetate and mixtures thereof.

38. The process of claim 35, wherein said hydrochloric acid is added in an alcoholic solution.